

REMARKS

Claims 1-4, 8-13 and 20 are pending in the application. Claims 14-19 and 21-34 have been previously withdrawn without prejudice. Claims 5-7 have been previously cancelled.

I. Claim Rejections – 35 U.S.C. §101

To properly determine whether a claimed invention complies with the statutory invention requirements of 35 U.S.C. § 101, the Office must first identify whether the claim falls within at least one of the four enumerated categories of patentable subject matter recited in section 101 (process, machine, manufacture or composition of matter). MPEP §2106 IV(B). The present claims are directed to a method and/or a process for predicting the soybean cyst nematode resistance of a soybean sample. Applicant respectfully submits that these claims fall within the useful process category within the meaning of 35 U.S.C. § 101.

Applicant recognizes that determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in 35 U.S.C. § 101 (process, machine, manufacture or composition of matter) does not end the analysis. Claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible and therefore are excluded from patent protection. Here again, the initial burden is for the examiner to weigh all the factors to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole falls within one of the exceptions to statutory subject matter. The Examiner fails to explain why the claims fall within one of the judicial exceptions, namely, an abstract idea, natural phenomenon, or law of nature. Indeed, the instant claims recite steps of performing a particular process such as obtaining a spectroscopic scan of a soybean sample to provide an assay spectra over a predetermined frequency range and comparing the assay spectra with a predictive model. *See, e.g.*, Claim 1. Such a claim is not directed to an abstract idea, a natural phenomenon, or a law of nature within the meaning of 35 U.S.C. § 101.

The Examiner misapplies the law by going into the analysis of whether the claimed invention “transforms” an article or physical object to a different state or thing or

whether the claimed invention otherwise produces a useful, concrete and tangible result. This analysis is misplaced because such an analysis is only necessary after it has been first determined that the claimed invention falls within one of the judicial exceptions, namely, an abstract idea, natural phenomenon, or law of nature. Because the Examiner has not established that the instant claims are either an abstract idea, a natural phenomenon, or a law of nature, the analysis of whether the invention produces useful, concrete and tangible results is not called for and is irrelevant.

MPEP 2106 IV(D) explicitly states that “[a]fter USPTO personnel identify and explain in the record the reasons why a claim is for an abstract idea with no practical application, then the burden shifts to the applicant to either amend the claim or make a showing of why the claim is eligible for patent protection.” Here, the Examiner must explain first why a claim is for an abstract idea, and then explain why it has no practical application. If the Examiner insists that the instant claims are directed to laws of nature, natural phenomena or abstract ideas, Applicant respectfully requests an explanation of why a process containing steps of obtaining a spectroscopic scan of a soybean sample and comparing the assay spectra with a predictive model is a law of nature, a natural phenomenon or an abstract idea, or the application thereof. Thus, because Applicant’s claimed invention fall within one of the statutory categories and fall outside of the exceptions, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 101.

II. Claim Rejections – 35 U.S.C. §103

Claims 1-4, 8, 10-13, and 20 stand rejected under 35 U.S.C. §103(a) as being obvious over Qiu et al. (Journal of Nematology, 1997, Vol. 29, 523-30) (“Qiu”), in view of Marek et al. (Crop Sci., 2000, vol. 40, p713-16) (“Marek”) and Rutherford (Journal of Chemical Ecology, 1998, Vol. 24, p1447-63) (“Rutherford”). Applicant respectfully disagrees with the Examiner's position that Claims 1-4, 8, 10-13, and 20 are obvious over Qiu in view of Marek and Rutherford. The cited references fail to teach or suggest the claim limitation wherein near infrared (NIR) spectroscopic data are used to predict soybean resistance to soybean cyst nematode (SCN), nor do they disclose the limitation wherein the assay spectra obtained from a soybean sample are compared with a

predictive model based on spectra data obtained from soybean varieties with known resistance or susceptibility to SCN to predict the SCN resistance or susceptibility of the soybean sample based upon the comparison results.

Obviousness is a question of law based on underlying factual inquiries. The factual inquiries (also known as the “Graham factual inquiries”) to be performed by the Examiner are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc., Federal Register, Vol. 72, No. 195, 57526-35, 57526 (October 10, 2007)(“Examination Guidelines” hereinafter). Once the Graham factual inquiries are resolved, the Examiner must determine whether the claimed invention would have been obvious to one of ordinary skill in the art. Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. Although the prior art reference (or references when combined) need not teach or suggest all the claim limitations, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. *Id.* 57528.

The Supreme Court noted in *KSR* that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court stated that ““rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”” *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 at 1741, 82 USPQ2d 1385 at 1396 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (C.A. Fed. 2006). The Court also reiterated the long-held tenet against a “temptation to read into the prior art the teachings of the invention in issue” and “against slipping into the use of hindsight.” *Id.*, at 1742, quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (C.A.6 1964).

Qiu examines chitinase activities in soybean plants before and after they are inoculated with a soybean root-knot nematode *Meloidogyne incognita*. Only two soybean strains were used for the study, namely, Brim (SCN susceptible) and Bryan (SCN resistant). Figure 1A of Qiu shows that the total chitinase activities were similar between the two strains under control condition, i.e., when the cultivars were not inoculated with the nematode. See page 526, Fig. 1A, see also page 526, left col. lines 5-8. Qiu went on to observe that the resistant cultivar had higher chitinase activity than the susceptible cultivar 10 days after soil infestation (DAL). See page 526, left col. line 10 to right Col. line 2. Based on these data, Qiu concluded that “the resistant cultivar had higher chitinase activity than the susceptible cultivar starting 3 DAL.” Page 528, left col., lines 20-22. Qiu went on to “speculate that the higher chitinase activity detected in the resistant cultivar Bryan could be associated with root-knot nematode resistance in soybean.” Page 528, left col., lines 25-29 (emphasis added). Recognizing the shortcomings that its studies are far from conclusive because of the small sample size and the use of non-isogenic strains, Qiu states that further studies “utilizing better-defined genetic material such as near isogenic lines or recombinant inbred lines are required.” Page 528, left col., line 29 to Page 528, right col., line 3. Taken together, Qiu at most shows that chitinase activity appears to be induced about 3 days after infestation and that there appears to be no difference in pre-infestation chitinase activity among strains that are resistant or susceptible to root-knot nematode.

Marek merely discloses that chitinase activity can be measured by NIR spectroscopy. Rutherford relates to a method for predicting sugarcane resistance to certain stalk borer. Neither Marek nor Rutherford teaches that chitinase activity in a soybean sample can predict the relative susceptibility of a soybean plant to SCN.

Applicant’s invention overcomes the problem unsolved by others by examining the SCN susceptibility of a statistically significant number of soybean strains and their chitinase activities. Applicant also takes advantage of near isogenic strains to obtain more accurate data showing the correlation between nematode susceptibility and chitinase activity in uninfected soybean samples. See, e.g., paragraph 51 of the original Specification.

Thus, at least three major differences exist between Applicant's claimed invention and the disclosure of the cited references. First, Applicant's invention is directed to predicting whether or not a given soybean sample is derived from a soybean plant that is resistant or susceptible to SCN. By contrast, Qiu never teaches that resistant and susceptible soybean strains exhibit different levels of chitinase before infestation. As explained above, Qiu discloses that resistant cultivar and susceptible cultivar only begin to show differences in chitinase activity 3 days after infestation. Having read Qiu, Marek and Rutherford, one of ordinary skill in the art would reasonably conclude that inoculation of a soybean with SCN is necessary in order to assess the susceptibility of a soybean strain. Thus, one of ordinary skill would not know that NIR scan of a soybean samples can be used to predict nematode susceptibility. This is so because the term "predict" means to foretell, or to declare in advance. To inoculate a soybean plant with a nematode in order to tell whether the plant is resistant or susceptible to said nematode does not constitute prediction.

Secondly, Qiu only examines the chitinase activity root and shoot samples of the soybean plant. Claim 3 of the instant application recites that the soybean sample is from the seed. It is well known that different tissues in the same plant may have drastically different gene expression profiles. Even if we assume that Qiu does disclose that chitinase activity in root and shoot samples may foretell nematode susceptibility, it does not necessarily true that chitinase activity in the seeds also indicate nematode susceptibility. Applicant does not understand why the Examiner believes that the combination of Qiu, Marek and Rutherford would render the invention of claim 3 obvious.

Lastly, even if Qiu does disclose that chitinase activity in root and shoot samples may be used to predict susceptibility of a soybean plant to root-knot nematode, it does not follow that these data can also be used to predict the susceptibility of a soybean plant to SCN. Root-knot nematode (*Meloidogyne incognita*) and SCN (*Heterodera glycines* Inchinohe) belong to different genera of nematodes and may have different modes of infection on different hosts. See, e.g. paragraph 7 of the original specification. Just because a soybean plant is resistant to one species of nematode does not necessarily mean that it is also resistant to another nematode species. All rejected claims include the

limitation of SCN. Applicant does not understand why the Examiner believes that the claimed invention would be obvious even though none of the references teach or suggest any means to predict soybean susceptibility to SCN.

The Examiner has not provided a convincing line of reasoning as to why a skilled artisan would find Applicant's discovery of the correlation between soybean susceptibility to SCN and chitinase activity obvious. Applicant notes that the Guidelines provides a number of sample rationales which can be used to support a obviousness rejection. However, none of those rationales can possibly support the Examiner's position because the differences between the cited art and the claimed invention are such that it is not obvious for one of ordinary skill to bridge the gap without conducting original and innovative experimentation to arrive at the Applicant's invention.

Although Qiu suggests using isogenic strains, Qiu does not specify which strains to use, and there are a large number of isogenic soybean strains to choose from. More importantly, the results of this type of experimentation is highly unpredictable. Thus, even under the "obvious to try" rationale, the instant invention is not obvious over the cited references because at least two of the requirements to substantiate an "obvious to try" rationale are missing. See Guidelines, at 57532, requiring "a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem" and "a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success" to support an "obvious to try" rationale.

Thus, because substantial differences exist between Applicant's claimed invention and the cited references, and because the Examiner has not advanced a reasonable rationale to support the legal conclusion that the claimed inventions are obvious over the cited art, withdrawal of the rejections is respectfully requested.

III. Claim Rejections – 35 U.S.C. §103

Claims 1, 8 and 9 stand rejected under 35 U.S.C. §103(a) as being obvious over Rutherford, in view of Qiu and Marek, and further in view of Borggaard et al. (Anal. Chem. 1992, 64:545-51) ("Borggaard"). Applicant disagrees with Examiner for reasons

discussed in the previous section with regard to Rutherford, Qiu and Marek, as well as reasons presented in the following text.

As discussed above, there is no teaching in Rutherford, Qiu and Marek that near infrared (NIR) spectroscopic data can be used to predict soybean resistance to SCN. Nor do these references disclose the limitation wherein the assay spectra obtained from a soybean sample are compared with a predictive model based on spectra data obtained from soybean varieties with known resistance or susceptibility to SCN to predict the SCN resistance or susceptibility of the soybean sample based upon the comparison results. The addition of Borggaard does not cure this deficiency because Borggaard does not teach comparing NIR spectra with a predictive model to predict SCN resistance or susceptibility. Withdrawal of the obviousness rejections is respectfully requested.

For the foregoing reasons, Applicant's attorney respectfully solicits a Notice of Allowance. The fee for a three month extension of time is submitted herewith. Applicant believes no additional fees are due at this time. However, if any fees are deemed necessary in connection with this filing, the Commissioner is hereby authorized to charge deposit account No. 12-0600.

Respectfully submitted,



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